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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/675,329

09/30/2003

Mark McCormick

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EXAMINER

GROSS, CHRISTOPHER M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/675,329	Applicant(s) MCCORMICK ET AL.	
	Examiner Christopher M. Gross	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Responsive to communications entered 12/13/2006. Claims 1-16 are pending. Claims 1-6, 14-16 are withdrawn. Claims 7-13 are examined herein.

Election/Restrictions

Applicant's election with traverse of Group II (Claims 7-13) in the reply filed on 05/0/2006 is again acknowledged.

Applicant has elected with traverse the following species for the elected invention group II (Claims 7-13) in the reply filed on 05/08/2006.

(a) For the single specific species of hapten, applicant elected "biotin."

(b) For the single specific species of reporter molecule, applicant elected "horseradish peroxidase."

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) [taken from MPEP 201.01]

The instant application has a filing date of 9/30/2003 and claims priority to provisional application 60415119 filed 9/30/2002. Nevertheless, "subarrays" are not disclosed in the provisional application.

Therefore 9/30/2003 is the date for the purposes of prior art concerning claims 7-13.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specification

The disclosure is objected to because of the following informalities: The brief description of the drawings indicates figure 1 as the chemical structure of 5'-Biotin Phosphoramidite, but the drawing provided shows two circles consisting of a series of dots. Appropriate correction is required.

Withdrawn Objections and Rejection(s)

The objection to claim 11 for depending on Claim 6, which is a product claim and not a method claim is hereby withdrawn in view of applicant's amendments.

The rejection of claims 7-13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention is hereby withdrawn in view of applicant's amendments.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites vague and indefinite language in "photopatterning a group-bearing phosphoramidite" in line 2.

It is noted that paragraph 0018 of the published application states "The term **photopatterning** as used herein is created by the mirrors of the MASTM instrument. The haptenylated border may be rendered visible by any chemical or enzymatic molecule or combination of molecules that provides a visual output depicting its location. The attachment of the illuminating compound is most easily done by attaching haptens to the array and then attaching fluorescent or light detectable compounds to the haptens."

Whereas in paragraph 0011 of the published application states "The last step in synthesis is the photodeprotection of the areas where visible borders are desired... This all occurs on the MASTM instrument."

To one of skill in the art, it is not clear whether the photopatterning step of claim 11 refers to photodeprotection by the MASTM instrument or else visualizing light detectable compounds in a particular pattern, or both. Furthermore, it is not clear how

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the latter step may be done by the MAS™ instrument, when it appears visualizing light detectable patterns is accomplished by enzymatic activity, for instance, rather than photolysis, therein the metes and bounds of claim 11 and dependent claim 12 are rendered unascertainable.

Claim 8 recites ambiguous grammar in lines 1 and 2: "the hapten comprises is a biotin or dinitrophenol (DNP)" To one of ordinary skill in the art, it is not clear if the limitation is directed to haptens comprising a biotin or DNP *functional group(s)* or rather biotin or DNP itself, thus making the metes and bounds of claim 8 unascertainable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 8, 11, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by **Noblett** (US Patent 6362004).

The claimed subject matter per claim 7 is drawn to a method for making a microarray having a plurality of subarrays surrounded by a visible or machine readable alignment mark in an interstitial region of the microarray, the method comprising the steps of:

a) selecting at least one probe set comprising probes of interest;

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- b) building the probe sets on a microarray slide to provide a plurality of subarrays; and
- c) depositing between subarrays a hapten and an illuminating compound to form the alignment mark between the subarrays on the microarray.

Claim 13 is drawn to the alignment mark being flexibly deployable within the array and can be placed with great precision immediately adjacent to and surrounding the subarray.

Noblett teaches, throughout the document and especially the title, an apparatus and method using fiducial marks on a microarray.

Noblett teaches fiducial marks surrounding a microarray as elements 127,125 and 119 in figure 1, which are taken as the alignment mark of claim 7. Noblett teaches subarrays in figure 7. Noblett teaches in column 2, line 15 the application of microarrays toward differential gene expression which is taken as the selecting step of claim 7. Noblett teaches [probe] spot application via a capillary dispenser column 6 line 35 which is taken as the building probe sets step of claim 7.

According to paragraph 0015 of the present published application, "The present invention also provides a method for the in situ synthesis of visible or machine readable (i.e., haptenylated) border regions" Thus the hapten deposition of claim 7 is taken as providing a machine readable portion of the microarray.

Noblett teaches in column 7, lines 30-36 illumination of said fiducial mark which is analyzed with the aid of a computation device, which is taken as machine readable, therein reading on the depositing step of claim 7.

Said various fiducial mark elements 127,125 and 119 according to Noblett is taken as providing an alignment mark [which] is flexibly deployable, as set forth in claim 13. Noblett teaches deposition using precise distances in column 6, line 51, which is taken as the great precision of claim 13.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-13 rejected under 35 U.S.C. 103(a) as being unpatentable over **Noblett** (US Patent 6362004) in view of **Zhu et al** (US Patent 6936416).

Noblett is relied on as above.

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Noblett do not teach biotin haptens (elected species of claim 8); streptavidin conjugates (claim 9) or horse radish peroxidase (HRP) reporters (elected species of claim 10).

Zhu et al teach, throughout the document and especially the abstract that certain human genes are induced or repressed in host cells infected with human cytomegalovirus (HCMV). In an effort to characterize said human genes, Zhu et al teach in column 17, line 64 through column 18, line 10 various signal detection methods based on biotin and various corresponding streptavidin conjugates, including HRP.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to employ the apparatus and method using fiducial marks on a microarray of Noblett et al to analyze human genes associated with HCMV infection using detection methods based on biotin and various corresponding streptavidin conjugates, including HRP per Zhu et al.

One of ordinary skill in the art would have been motivated to make the apparatus and method using fiducial marks on a microarray of Noblett et al to analyze the human genes of associated with HCMV infection using detection methods based on biotin and various corresponding streptavidin conjugates, including HRP per Zhu et al because such genes are likely related to the pathology of infected tissues which would enable one to find therapeutic agents to treat HCMV-caused disease, as noted by Zhu et al in the abstract.

One of ordinary skill in the art would have had a reasonable expectation of success in studying the human genes of associated with HCMV infection based on

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biotin and various corresponding streptavidin conjugates, including HRP per Zhu et al with the apparatus and method using fiducial marks on a microarray of Noblett because Zhu et al teach in columns using 11-17 the applicability of high density arrays toward such studies. Therein said studies of human genes associated with HCMV infection according to Zhu et al lies well within the scope of the microarray-based analysis advocated by Norbett.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

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J. DOUGLAS SCHULTZ, PH.D.
SUPERVISORY PATENT EXAMINER